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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,539	06/06/2001	Victor C.W. Tsang	14114.0358U2	6357

52488 7590 10/14/2005

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EXAMINER	
NGUYEN, BAO THUY L	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,539	TSANG ET AL.	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *6-16 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,17,18 and 20* is/are rejected.

7)☒ Claim(s) *5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment submitted 01 August 2005 has been received.

2. Claims 1-5, 17, 18 and 20 are pending. Claims 6-16 and 19 are withdrawn.

Claim Rejections - 35 USC § 102

3. Claims 1-4, 17-18, and 20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Perryman et al (WO 98/07320) for reasons of record which is reiterated herein below.

Perryman discloses antibodies specific to C. *parvum* sporozoites. See pages 13, 14, 17 and 19.

4. Claims 1-4, 17-18 and 20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Petersen et al., *Infection and Immunity*. 1992. Vol. 60, No. 12, pp. 5132-5138 for reasons of record which is reiterated herein below.

Petersen discloses monoclonal antibodies to a soluble C. parvum sporozoite glycoprotein. See pages 5133-5137.

5. Claims 1-4, 17-18 and 20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Riggs et al (WO 97/36612) for reasons of record which is reiterated herein below.

Riggs discloses compositions comprising monoclonal antibodies to C. parvum sporozoite. See pages 4-6.

Allowable Subject Matter

6. Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fails to disclose the monoclonal antibody having ATCC designation CRL-12604.

Response to Arguments

8. Applicant's arguments filed 01 August 2005 have been fully considered but they are not persuasive.

Applicant argues that the instant claims are drawn to an antibody that is "specific for a soluble antigen of a C. parvum sporozoite" and that Perryman does not anticipate these claims because the antigen taught by Perryman, p23, can be obtained from merozoites, therefore, this antigen is not specific to sporozoites.

This is not persuasive. The claims state that the *antibody* has to be *specific* for a soluble antigen of C. parvum sporozoite. The claims do not require that the *antigen* have to be specific to sporozoite. The definition of "an antibody *specific for*" was previously argued by Applicant and responded to in the previous office action (pages 5 and 6 of the Office action dated 3/9/2005).

The argument that the antigen of Perryman is the same as the antigen taught by Moss and Bonafonte is not persuasive. As stated above, the claims are not drawn to an *antigen specific to the sporozoites*, therefore, this argument is not on point.

Applicant argues that Petersen does not anticipate the instant claims because the antibodies taught by Petersen are reactive with a gp900 glycoprotein found in both the merozoites and sporozoites. Therefore, the gp900 is not specific to the sporozoites.

This argument is not persuasive for the same reason stated above. The claims are directed to *an antibody* that is *specific for* a soluble antigen of a C. parvum sporozoite. The claims do not require that the *antigen* has to be exclusively found in the sporozoite. Applicant provided an article, Paul (Exhibit A), that defines the term *specific for* and consistent with this definition, the antibodies taught by Perryman and Petersen are *specific for* a soluble antigen of a C. parvum sporozoite.

Applicant argues that Riggs does not anticipate the instant claims because the GP25-200 complex of Riggs is not specific to the sporozoites.

This argument is not persuasive for the same reasons stated above. Mainly, the claims do not require that the *antigen* is *specific for* the sporozoites.

Applicant also argues that because the antigen recognized by the C4A1 mAb comigrated with bands of similar molecular weight derived from whole organisms, that this antigen could have also been derived from whole organism and therefore not specific for sporozoites.

Even though this argument is not on point since the claims do not require the antigen to be specific for sporozoites, it is also not persuasive for other reasons. Mainly, Riggs clearly teaches that the antigen is prepared from solubilized sporozoites and separated on polyacrylamide gel, etc. Riggs states that the results obtained using this method confirmed that the immunoaffinity purification procedure was useful for purifying native sporozoite constituents. Riggs further teaches that immunoreactive bands of these antigens comigrated with bands of similar molecular weight derived from whole organisms and that this suggests that the antigenic target of C4A1 mAb is not a single species (i.e. a single antigen) but is a small number of antigens that shared the same epitope. This teaching cannot be interpreted that the antigen could have been derived from whole organisms. It only teaches that C4A1 mAb binds to more than one antigen that either has the same epitope or shares the same epitope.

The argument that it is incorrect to characterize the experiment taught by Riggs as disclosing that 112 hybridomas were found to positively bind to sporozoite as antigenic targets is not persuasive. Applicant argues that the 112 hybridomas were identified in a "preliminary indirect immunofluorescence assay" and that subsequently five of the mAbs tested in the live indirect immunofluorescence assay were found to bind to sporozoites and also to oocyst walls. Therefore, not all 112 hybridomas were tested for specificity sporozoites and only five were found to bind oocyst walls. Instead, the five that were found to bind sporozoites also bind with oocyst walls.

The following is a direct quote from the Riggs reference: "Preliminary indirect immunofluorescence assays using heat-fixed sporozoites as antigenic targets were used to identify hybridomas having specificity for GP 25-200. Results from this preliminary screening indicated that 112 of the hybridomas were positive for sporozoite binding." Page 6. GP 25-200 is disclosed as antigens with shared epitopes purified from solubilized sporozoite. Riggs also teaches that hybridoma culture supernatants were screened for surface-reactive anti-GP25-200 antibody by live indirect immunofluorescence. Riggs does not teach, as suggested by Applicant, that only 5 mAbs were further tested in the live indirect immunofluorescence. Of all of the mAbs tested using the live indirect immunofluorescence, 5 were found to bind to shed antigens. Page 7. The 5 that bind shed antigens also bind to oocyst walls. Therefore, the conclusion from the teaching of Riggs is that out of all of the mAbs that were tested, 5 were found to also bind oocyst walls, therefore, the majority of mAbs binds specifically to soluble sporozoite antigens.

Conclusion

9. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Wednesday from 8:00 a.m. -4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BAO-THUY L. NGUYEN
PRIMARY EXAMINER
10/12/05